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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,687	11/21/2005	Sam A. Deadwyler	C21-074US	4031

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EXAMINER	
KIM, JENNIFER M	
ART UNIT	**PAPER NUMBER**
1628	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/541,687	DEADWYLER ET AL.	
	Examiner	Art Unit	
	JENNIFER M. KIM	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-33 and 35* is/are pending in the application.

4a) Of the above claim(s) *4-13 and 20-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 14-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/3/2005;1/8/2007;2/6/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election **with traverse** of **Group V** (claims 1-3 and 14-19) drawn to a method for treating or preventing cognitive impairment comprising administering an AMPA receptor potentiator having a compound of structure set forth in claim 2 with a **1-(benzofuranzan-5-ylcarbonyl)morpholine (BCM)** as a species of potentiator is acknowledged. The traversal is on the ground(s) that although Group V and Group VII are closely related. Therefore, no serious burden would be placed on the Examiner if restriction was not required. This is not found to be persuasive because that the compounds in Groups V and VII are drawn to independent and patentably distinct subject matter because the inventions have acquired a separate status in the art in view of their different classification. Moreover, the compounds in Group V having the bicyclic ring set forth in claim 2 have completely different physical/chemical characteristic than the compounds in Group VII having tricyclic ring set forth in claim 6. Accordingly, the ring systems and the radicals therein are independent and patentably distinct. The searches are not co-extensive and there is a serious burden placed on the Examiner to search the entire scope of claims when multiple unrelated inventions are claimed. Therefore, the restriction requirement made in the last Office Action is deemed proper and made final.

Accordingly, claims 1-3 and 14-19 have been examined only to the extent of Applicants' elected species. Claims 4-13, 20-33 and 35 are withdrawn from consideration since they are non-elected invention.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-3 and 14-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the "treatment of cognitive impairment", does not reasonably provide enablement for the "**prevention of** cognitive impairment". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

3. Enablement is considered in view of the Wands factors (MPEP 2164.01(a)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, predictability of the prior art, state of the prior art and the amount of experimentation necessary. All of the **Wands factors** have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the Invention: All of the rejected claims are drawn to a method for treating or **preventing** cognitive impairment as a result of acute or chronic sleep deprivation, comprising administering to a subject or patient an effective amount of an AMPA receptor potentiator (i.e. BCM) such that the subject treated with above compounds does not develop cognitive impairment.

Breath of the Claims: The complex of nature of the claims greatly exacerbated by breath of the claims. The claims encompass actual **prevention** of cognitive impairment as a result of acute or chronic sleep deprivation.

Guidance of the Specification: The guidance given by the specification as to how one would administered the claimed compounds to a subject in order to prevent cognitive impairment due to sleep deprivation is minimal. All of the guidance provided by the specification is directed towards **treatment or alleviation rather than prevention** of cognitive impairment.

Working Examples: All of the working examples provided by the specification are directed toward the **treatment and/or alleviation rather than prevention** of cognitive impairment due to sleep deprivation.

State of the Art: While the state of the art is relatively high with regard to treatment of cognitive impairment, the state of the art with regard to **prevention** of such disorders is underdeveloped. In particular, there do not appear to be any examples or teachings in the prior art wherein a compound similar to the claimed compounds was administered to a subject to **prevent** development of cognitive

impairment resulted from sleep deprivation. The state of the art, Rogers et al. (U.S.Patent No. 6,313,115 B1) teaches the compound having AMPA receptor enhancing properties are useful for **alleviating or treating** conditions such as memory impairment. (abstract, Examples and claims). However, there are no examples **preventing** such disorder with the compound to halt the development of cognitive impairment resulted from sleep deprivation.

Predictability of the Art*:* The lack of significant guidance from the specification or prior art with regard to the **actual prevention** of cognitive impairment resulted from sleep deprivation in a human subject with the claimed compounds makes practicing the claimed invention unpredictable in terms of prevention of cognitive sleep deprivation.

The amount of Experimentation Necessary*:* In order to practice claimed invention, one of skilled in the art would have to first envision a combination of appropriate pharmaceutical carrier, compound dosage, duration of treatment, route of administration, etc. and appropriate animal model system for one of the claimed compounds and test the combination in the model system to determine whether or not the combination is effective for prevention of cognitive impairment. If unsuccessful, which is likely given the lack of significant guidance from the specification or prior art regard **prevention** of cognitive impairment with any compound, one of skill in the art would have to then either envision a modification of the first combination of pharmaceutical compound, compound dosage, duration of treatment, route of administration, etc. and appropriate animal model

system, or envision an entirely new combination of the above, and test the system again. If again unsuccessful, which is likely given the lack of significant guidance form the specification of prior art regarding prevention of cognitive impairment with any compound, the entire, unpredictable process would have to be repeated until successful. Therefore, it would require undue, unpredictable experimentation to practice the claimed invention to prevent the development of cognitive impairment in a subject by administration of one of the claimed compounds.

Therefore, a method for treating or **preventing** cognitive impairment as a result of acute or chronic sleep deprivation, comprising administering to a subject or patient an effective amount of an AMPA receptor potentiator (i.e. BCM) is not considered to be enabled by the instant specification.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3 and 14-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rogers et al. (U.S.Patent No. 6,313,115 B1).

Rogers et al. teach Applicants elected compound, **4-benzofurazan-5-ylcarbonyl)morpholine**, useful for the alleviating **impairment of memory or other cognitive functions,** brought on by a deficiency in the number or strength of excitatory synapses or in the number of AMPA receptors. (see Example 9, column 6, lines 62-66, column 10, lines 45-49, column 22, claims 17 and 21). Rogers et al. teach that the treatment can be also used in humans, domesticated animals and laboratory animals. (column 10, lines 55-65).

Rogers et al. do not expressly teach the acute or chronic sleep deprivation as a cause of the cognitive impairment and the specified patient populations set forth in claims 16-19.

It would have been obvious to one of ordinary skill in the art to employ 4-benzofurazan-5-ylcarbonyl)morpholine in the treatment of cognitive disorder or impairment of memory functions at any cause including acute or chronic sleep deprivation because Rogers et al. teach that the composition comprising 4-benzofurazan-5-ylcarbonyl)morpholine is useful for the treatment of impairment in memory or other cognitive functions in general particularly for the subject population of humans and animals. With regard to the administration of the compound for the

treatment of cognition impairment to the specific patient population set forth in claims 16-19, such is obvious because the instant compound to be utilized is disclosed by Rogers et al having therapeutic use in the treatment of memory impairment and other cognitive disorder, it would have been obvious to one of ordinary skill in the art to this utility would be retained upon the administration of the compound to any subject populations in humans and animals.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER M. KIM whose telephone number is (571)272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax

phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JENNIFER M KIM/
Primary Examiner, Art Unit 1617

Jmk
September 17, 2009